4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-D-2024]

Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act." This guidance clarifies the enhanced drug distribution security requirements listed in the Federal Food, Drug, and Cosmetic Act (FD&C Act). In addition, this guidance outlines and makes recommendations on the system attributes necessary to enable secure tracing of product at the package level, including allowing for the use of verification, inference, and aggregation, as necessary. This guidance finalizes the draft guidance of the same title issued on June 4, 2021.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment

does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2020-D-2024 for "Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT

CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002, or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Abha Kundi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3130, drugtrackandtrace@fda.hhs.gov; or Anne Taylor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act." The Drug Supply Chain Security Act (DSCSA) (Title II of Pub. L. 113-54) was signed into law on November 27, 2013.

The DSCSA outlines critical steps to achieve electronic pharmaceutical supply chain interoperability by November 27, 2023, that will enhance the identification and tracing of certain prescription drugs as they are distributed within the United States. Section 202 of the DSCSA added section 582 to the FD&C Act (21 U.S.C. 360eee-1), which established product tracing, product identifier, authorized trading partner, and verification requirements for manufacturers, repackagers, wholesale distributors, and dispensers to facilitate the tracing of products through the pharmaceutical distribution supply chain. Section 582 of the FD&C Act also imposed requirements for enhanced drug distribution security that go into effect on November 27, 2023.

Trading partners, along with Federal and State authorities, have an important role in ensuring the quality of prescription drugs and protecting the integrity of the pharmaceutical distribution supply chain. The DSCSA requirements, which have been phased in since 2013, improve supply chain security activities by trading partners involved in prescription drug manufacturing, repackaging, wholesale distribution, warehousing or related logistical activities, and dispensing. The gradual implementation of the DSCSA requirements for product tracing, product identification, authorized trading partners, and verification facilitates the development of

electronic interoperability to enhance the security of the pharmaceutical distribution supply chain.

Section 582(g)(1) of the FD&C Act sets forth the requirements for enhanced drug distribution security as of November 27, 2023, including (as described in that provision and generally summarized here):

- The exchange of transaction information and transaction statements in a secure, interoperable, electronic manner.
- Transaction information that includes the product identifier at the package level for each package included in the transaction.
- Systems and processes for verification of product at the package level.
- Systems and processes needed to promptly respond to requests from FDA (or other appropriate Federal or State officials) for product transaction information in the event of a recall or to investigate suspect and illegitimate products.

This guidance clarifies the enhanced drug distribution security requirements and pursuant to section 582(h)(3) of the FD&C Act describes recommendations for system attributes necessary for enhanced product tracing and enhanced verification, including when the use of aggregation and inference may be appropriate.

This guidance finalizes the draft guidance entitled "Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act" issued on June 4, 2021 (86 FR 30053). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include removal of the term "enhanced system" when referring to the requirements in section 582(g) of the FD&C Act to avoid confusion and clarification of recommendations addressing (1) reconciliation of transaction information, (2) aggregation and inference, and (3) verification of saleable returns, including a brief discussion of the sunset provisions of section 582(k) of the FD&C Act. Changes also include clarification of requirements for provision of certain information in response to requests

stemming from investigation of suspect or illegitimate product. In addition, editorial changes were made to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Enhanced Drug Distribution Security at the Package Level Under the Drug Supply Chain Security Act." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance includes information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent substantive or material modifications to those previously approved collections of information found in FDA regulations or guidance.

III. Electronic Access

Persons with access to the internet may obtain the guidance at https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or https://www.regulations.gov.

Dated: August 28, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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